SENNA- senna tablet, coated Aphena Pharma Solutions - Tennessee, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Repackaging Information

Please reference the *How Supplied* section listed above for a description of individual tablets. This drug product has been received by Aphena Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphena are listed below:

Count	8.6 mg
100	71610-054-65

Store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:

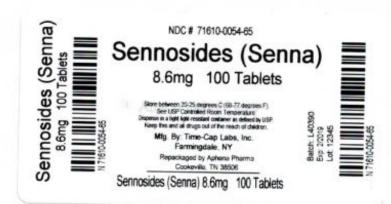


Cookeville, TN 38506

20180427JH

PRINCIPAL DISPLAY PANEL - 8.6 mg

NDC 71610-054 - Sennosides (Senna) 8.6 mg - Rx Only



SENNA

senna tablet, coated

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:71610-054(NDC:0904-6434) Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SENNOSIDES A AND B (UNII: 1B5FPI42EN) (SENNOSIDES A AND B - UNII:1B5FPI42EN)	SENNOSIDES A AND B	8.6 mg		

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)			
DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)			
HYPROMELLOSES (UNII: 3NXW29 V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			
MINERAL O IL (UNII: T5L8T28FGP)			

Product Characteristics				
Color	bro wn	Score	no score	
Shape	ROUND	Size	9 mm	
Flavor		Imprint Code	TCL080	
Contains				

Packaging			
# Item Code Package Description		Marketing Start Date	Marketing End Date
1 NDC:71610-054-65	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 4/26/20 18	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	06/09/2015		

Labeler - Aphena Pharma Solutions - Tennessee, LLC (128385585)

Establishment				
Name	Address	ID/FEI	Business Operations	
Aphena Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-054)	